

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:) Group Art Unit: 3733
RITLAND)
Serial No.: 10/776,094) Confirmation No.: 2357
Filed: February 10, 2004)
Atty. File No.: 4510-1-DIV) Examiner: PHILOGENE, PEDRO
For: "POLYAXIAL CONNECTION)
DEVICE AND METHOD")
DISCLOSURE STATEMENT
Electronically Submitted

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The references cited on attached Form PTO-SB08 are being called to the attention of the Examiner.

- Copies of the cited non-patent and/or foreign references are enclosed herewith.
- Copies of the cited U.S. patents and/or patent applications are enclosed herewith.
- Copies of the cited U.S. patents/patent application publications are not enclosed in accordance with 37 C.F.R. § 1.98(a).
- Copies of the cited references are not enclosed, in accordance with 37 C.F.R. § 1.98(d), because the references were cited by or submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____ filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120.
- To the best of applicants' belief, the pertinence of the foreign-language references are believed to be summarized in the attached English abstracts and in the figures, although applicants do not necessarily vouch for the accuracy of the translation.
- Examiner's attention is drawn to the following co-pending applications, copies of which have been or are being submitted:

Serial No. 11/425,987 filed 06-22-06

Other: _____

Submission of the above information is not intended as an admission that any item is citable under the statutes or rules to support a rejection, that any item disclosed represents analogous art, or that those skilled in the art would refer to or recognize the pertinence of any reference without the benefit of hindsight, nor should an inference be drawn as to the pertinence of the references based on the order in which they are presented. Submission of this statement should not be taken as an indication that a search has been conducted, or that no better art exists.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application and the references made of record therein.

FEES

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|-------------------------------------|--|
| <input type="checkbox"/> | <p>37 CFR 1.97(b): No fee is believed due in connection with this submission, because the information disclosure statement submitted herewith satisfies one of the following conditions ("X" indicates satisfaction):</p> <ul style="list-style-type: none"><input type="checkbox"/> Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or<input type="checkbox"/> Within three months of the date of entry into the national stage of an international application as set forth in 37 CFR 1.491 or<input type="checkbox"/> Before the mailing date of a first Office Action on the merits, or<input type="checkbox"/> Before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114. <p>Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</p> |
| <input checked="" type="checkbox"/> | <p>37 CFR 1.97(c): The information disclosure statement transmitted herewith is being filed after all the above conditions (37 CFR 1.97(b)), but before the mailing date of one of the following conditions:</p> <ul style="list-style-type: none">(1) a final action under 37 C.F.R. 1.113 or(2) a notice of allowance under 37 C.F.R. 1.311, or(3) an action that otherwise closes prosecution in the application. <p>This Information Disclosure Statement is accompanied by:</p> <ul style="list-style-type: none"><input type="checkbox"/> A Certification (below) as specified by 37 C.F.R. 1.97(e). Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970. <p>OR</p> <ul style="list-style-type: none"><input type="checkbox"/> Please charge Deposit Account 19-1970 in the amount of \$180.00 for the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement. Please credit any overpayment or charge any underpayment to Deposit Account 19-1970. |
| <input type="checkbox"/> | <p>37 CFR 1.97(d): This Information Disclosure Statement is being submitted after the period specified in 37 CFR 1.97(c).</p> <ul style="list-style-type: none"><input type="checkbox"/> This information Disclosure Statement includes a Certification (below) as specified by 37 C.F.R. 1.97(e) AND<input type="checkbox"/> Applicants hereby requests consideration of the reference(s) disclosed herein. Please charge Deposit Account 19-1970 in the amount of \$180.00 under 37 C.F.R. 1.17(p). Please credit any overpayment or charge any underpayment to Deposit Account 19-1970. Election to pay the fee should not be taken as an indication that applicant(s) cannot execute a certification. |

Certification (37 C.F.R. 1.97(e))
(Applicable only if checked)

The undersigned certifies that:

- Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(1).
- A copy of the communication from the foreign patent office is enclosed.

OR

- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(2).

Respectfully submitted,

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By: _____



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Date: January 11, 2007

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| Substitute for form 1449A/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/776,094 |
| | | | | Filing Date | 02/10/04 |
| | | | | First Named Inventor | Ritland |
| | | | | Art Unit | 3733 |
| | | | | Examiner Name | PHILOGENE, PEDRO |
| Sheet | 1 | of | 4 | Attorney Docket Number | 4510-I-DIV |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-kind Code ^{2 (if known)} | Publication Date MM-DD-YYYY | Name of Patentee of Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1 | 2,191 | 07/23/1841 | Pitney | |
| | 2 | 605,652 | 06/14/1898 | Pitt | |
| | 3 | 1,090,746 | 3/17/1914 | Nourse | |
| | 4 | 1,097,978 | 5/26/1914 | Johnson | |
| | 5 | 3,467,079 | 9/16/1969 | James | |
| | 6 | 3,893,454 | 7/18/1975 | Hagelin | |
| | 7 | 4,889,112 | 12/26/1989 | Schachner et al. | |
| | 8 | 4,995,875 | 2/26/1991 | Coes | |
| | 9 | 5,018,507 | 5/28/1991 | Montaldi | |
| | 10 | 5,026,373 | 6/25/1991 | Ray et al. | |
| | 11 | 5,030,223 | 07/09/1991 | Anderson et al. | |
| | 12 | 5,217,007 | 6/8/1993 | Ciaglia | |
| | 13 | 5,306,275 | 4/26/1994 | Bryan, Donald W. | |
| | 14 | 5,330,474 | 7/19/1994 | Lin, Chih-I | |
| | 15 | 5,499,983 | 3/19/1996 | Hughes, Dean | |
| | 16 | 5,501,684 | 3/26/1996 | Schlapfer et al. | |
| | 17 | 5,558,622 | 9/24/1996 | Greenberg | |
| | 18 | 5,569,300 | 10/29/1996 | Redmon | |
| | 19 | 5,584,833 | 12/17/1996 | Fournet-Fayard et al. | |
| | 20 | 5,683,392 | 11/4/1997 | Richelsoph, et al. | |
| | 21 | 5,716,355 | 2/10/1998 | Jackson, et al. | |
| | 22 | 5,735,850 | 4/7/1998 | Baumgartner, et al. | |
| | 23 | 5,772,582 | 6/30/1998 | Huttner et al. | |
| | 24 | 5,785,648 | 7/28/1998 | Min | |
| | 25 | 5,797,912 | 8/25/1998 | Runciman, et al. | |
| | 26 | 5,810,816 | 9/22/1998 | Roussouly, et al. | |
| | 27 | 5,810,817 | 9/22/1998 | Roussouly, et al. | |
| | 28 | 5,938,663 | 8/17/1999 | Petreto, Eric | |
| | 29 | 5,976,135 | 11/2/1999 | Sherman, et al. | |
| | 30 | 6,004,322 | 12/21/1999 | Bernstein | |
| | 31 | 6,027,533 | 2/22/2000 | Olerud, Sven | |
| | 32 | 6,146,383 | 11/14/2000 | Studer, et al. | |
| | 33 | 6,176,861 | 1/23/2001 | Bernstein et al. | |
| | 34 | 6,187,005 | 2/13/2001 | Brace et al. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.

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|-------|---|----|---|--------------------------|------------------|
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| | | | | Attorney Docket Number | 4510-1-DIV |

| | | | | |
|----|--------------|------------|-------------------------|--|
| 35 | 6,231,575 | 5/15/2001 | Krag, Martin H. | |
| 36 | 6,248,104 | 6/19/2001 | Chopin et al. | |
| 37 | 6,273,914 | 8/14/2001 | Papas | |
| 38 | 6,302,842 | 10/16/2001 | Auerbach et al. | |
| 39 | 6,309,390 | 10/30/2001 | Le Couedic, et al. | |
| 40 | 6,309,391 | 10/30/2001 | Crandall, et al. | |
| 41 | 6,355,038 | 3/12/2002 | Pisharodi | |
| 42 | 6,361,541 | 3/26/2002 | Barnhart | |
| 43 | 6,425,901 | 7/30/2002 | Zhu et al. | |
| 44 | 6,443,953 | 9/3/2002 | Perra, et al. | |
| 45 | 6,461,359 | 10/8/2002 | Tribus, et al. | |
| 46 | 6,478,798 | 11/12/2002 | Howland, Robert S. | |
| 47 | 6,579,292 | 6/17/2003 | Taylor, Harold Sparr | |
| 48 | 6,585,738 | 7/1/2003 | Mangione, et al. | |
| 49 | 6,595,993 | 7/22/2003 | Donno, et al. | |
| 50 | 6,610,062 | 8/26/2003 | Bailey, et al. | |
| 51 | 6,626,904 | 9/30/2003 | Jammet, et al. | |
| 52 | 6,626,906 | 9/30/2003 | Young | |
| 53 | 6,648,887 | 11/18/2003 | Ashman, Richard B. | |
| 54 | 6,671,725 | 12/30/2003 | Noel, Jr. et al. | |
| 55 | 6,676,661 | 1/13/2004 | Martin Benlloch, et al. | |
| 56 | 6,685,705 | 2/3/2004 | Taylor, Harold Sparr | |
| 57 | 6,743,257 | 6/1/2004 | Castro | |
| 58 | 6,749,613 | 6/15/2004 | Conchy, et al. | |
| 59 | 6,783,528 | 8/31/2004 | Vincent-Prestigiacomo | |
| 60 | 6,974,480 | 12/13/2005 | Messerli, et al. | |
| 61 | 2003/0109880 | 6/12/2003 | Shirado, et al. | |
| 62 | 2003/0139812 | 7/24/2003 | Garcia, et al. | |
| 63 | 2004-0138534 | 7/15/2004 | Ritland | |
| 64 | 2005/0027360 | 2/3/2005 | Webb, et al. | |
| 65 | 2005/0143737 | 6/30/2005 | Paffard, et al. | |
| 66 | 2005/0149191 | 7/7/2005 | Cragg, et al. | |
| 67 | 2005/0203517 | 9/15/2005 | Jahng, et al. | |
| 68 | 2005/0203519 | 9/15/2005 | Harms, et al. | |
| 69 | 2005/0209694 | 9/22/2005 | Loeb | |
| 70 | 2005-0149023 | 7/7/2005 | Ritland | |
| 71 | 2005-0228233 | 10/13/2005 | Ritland | |
| 72 | 2006/0009768 | 1/12/2006 | Ritland | |

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| | | | | Attorney Docket Number | 4510-1-DIV |

| | | | | | |
|--|----|--------------|-----------|---------------|--|
| | 73 | 2006/0041259 | 2/23/2006 | Paul, et al. | |
| | 74 | 2006/0064090 | 3/23/2006 | Park | |
| | 75 | 2006/0069390 | 3/30/2006 | Frigg, et al. | |
| | 76 | 10/165,991 | | Simonson | |
| | 77 | 11/425,987 | | Ritland | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---------------------------------|-----------------------|---|------------------|---|---|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ ; Number ⁴ ; Kind Code ⁵ (if known) | MM-DD-YYYY | | | |
| | 78 | FR 2796828 | 2/2/2001 | Jammet et al. | | Believed to correspond to U.S. Patent No. 6,626,904 cited above |
| | 79 | WO 99/40866 | 8/19/1999 | Elberg | | |

| OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.) | | |
|---|-----------------------|--|
| Examiner Initials* | Cite No. ¹ | |
| | 80 | China Chemical Reporter, "Rapid Development of Polyether Ether Ketone", CNCIC Chemdata Inc., 2004, 2 pages. |
| | 81 | Green, "Body Building - Medical Materials for Systems and Scaffolding," Materials World, Journal of the Institute of Materials, Vol. 10, No. 2, 2001, 4 pages. |
| | 82 | Green, "Effects of Gamma Sterilisation on Implant Grade Polyetheretherketone," Invibio Inc., Lancashire, United Kingdom, undated, 1 page. |
| | 83 | Green, "In Vivo Biostability Study on Polyaryletheretherketone Biomaterial," Invibio Inc., Lancashire, United Kingdom, undated, 2 pages. |
| | 84 | Green, et al., "A Polyaryletherketone Biomaterial for Use in Medical Implant Applications," Lancashire, United Kingdom, 2001, 1 page. |
| | 85 | Green, et al., "Polyetheretherketone Polymer and Compounds for Surgical Applications," Lancashire, United Kingdom, undated, 9 pages. |

| | | |
|--------------------|--|-----------------|
| Examiner Signature | | Date Considered |
|--------------------|--|-----------------|

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| | | | | Examiner Name | PHILOGENE, PEDRO |
| Sheet | 4 | of | 4 | Attorney Docket Number | 4510-1-DIV |

| | | |
|--|----|--|
| | 86 | Green, Stuart, "PEEK-Optima Polymer in the Implantable Medical Device Industry," Invibio Inc., Lancashire, United Kingdom, undated, 2 pages. |
| | 87 | Invibio, Biomaterials Solutions, "High Performance PEEK-Optima Biocompatible Polymer Chosen for Dental Abutment Healing Caps," Invibio Inc., Lancashire, United Kingdom, undated, 1 page. |
| | 88 | Invibio, Biomaterials Solutions, "High Performance PEEK-Optima Biocompatible Polymer Chosen for New Generation Heart Valve," Invibio Inc., Lancashire, United Kingdom, undated, 1 page. |
| | 89 | Invibio, Biomaterials Solutions, "PEEK-Classix," Invibio Inc., Lancashire, United Kingdom, 2003, 2 pages. |
| | 90 | Invibio, Biomaterials Solutions, "PEEK-Optima Polymer: Performance Purity Flexibility Endurance," Invibio Inc., Lancashire, United Kingdom, 2004, 3 pages. |
| | 91 | Invibio, Biomaterials Solutions, "PEEK-Optima, Composite Hip," Invibio Inc., Lancashire, United Kingdom, undated, 2 pages. |
| | 92 | Invibio, Biomaterials Solutions, "PEEK-Optima, Spiked Washers," Invibio Inc., Lancashire, United Kingdom, undated, 1 page. |
| | 93 | Sofamor Danek Video Systems Brochure |
| | 94 | Tangram Technology Ltd., "Polymer Data File: Polyether Ether Ketone-PEEK," Available at http://www.tangram.co.uk/TI-Polymer-PEEK.html , 2001, 5 pages. |
| | 95 | Web pages, http://www.brainlab.com , April 2, 2002; 5 pp. |
| | 96 | "New Minimally Invasive Techniques, Improve Outcome of Spine Surgeries", Medtronic Sofamor Danek. |
| | 97 | Kambin; "Percutaneous Posterolateral Discectomy"; Clinical Orthopaedics and Related Research, Section II; pp. 145-154. |

| | | |
|--------------------|--|-----------------|
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